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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,258	05/24/2006	Isabel Ottinger	33568-US-PCT	3217

1095 7590 08/22/2007

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,258	OTTINGER, ISABEL	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Claims 27-28 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

1. Applicant's arguments filed June 14, 2007 have been fully considered but they are not persuasive.

2. ***Rejection Maintained, Claim Rejections - 35 USC § 102*** The rejection of claims 1-4, 6-8 and 26 under 35 U.S.C. 102(e) as being anticipated by Silver et al (PG-Pub 2005/0209141 A1 effective filing date October 17, 2003) is traversed on the grounds that the compositions of Silver et al are dosage forms for local administration and Silver says nothing about a pharmaceutical composition for oral administration such as that of the present invention.

3. It is the position of the examiner that the recited intended use of the claimed compositions does not impart structural differences in the composition relative to the applied prior art. Silver et al disclose the instantly claimed invention directed to a composition that comprises Aliskiren (see [0070], rennin inhibitors), which is a gamma-amino-delta-hydroxy-omega-aryl-alkanoic acid amide rennin inhibitor, formulated into a microemulsion (see Silver paragraph [0150]), wherein the microemulsion comprises one or more organic solvent(s) that is/are acceptable from the physiological standpoint, chosen, in addition to water, from solvents

such as acetone, ethanol, isopropyl alcohol, glycol ethers such as the products sold under the name "Dowanol," polyglycols and polyethylene glycols, C.sub.1-C.sub.4 alkyl esters of short-chain acids, ethyl or isopropyl lactate, fatty acid triglycerides such as the products marketed under the name "Miglyol," isopropyl myristate, animal, mineral and vegetable oils and polysiloxanes together with an adjuvant chosen from antioxidants, surfactants, other preservatives, film-forming, keratolytic or comedolytic agents, perfumes, flavorings and colorings. Silver also discloses a method that comprises the step of administering Aliskiren to a patient (see claim 24) The method of claim 17, wherein the composition that can inhibit renin activity comprises BILA2157, **aliskiren**, remikiren, ankiren or enalkiren

Additionally, the instant Specification on page 1, paragraph [003], sites US Pat. 5,633,226 for teaching the direct administration of the compositions to a subject. Upon consideration of the definition of administration provided in US Pat. 5,633,226 , the examiner found at col. 3, line 21, disclosure for the compositions to be administered by oral or by injection. This section of the patent is being quoted immediately below:

" One aspect of the invention is the storage or maintenance of materials, such as proteins and peptides, in a solubilized state at temperatures or conditions at which they would otherwise be unstable. For example, it has been found that some proteins can be stored dissolved in the aqueous phase of the w/o microemulsions at temperatures at which the protein would be unstable if stored merely as an aqueous solution. Such proteins may be stored in a w/o microemulsion of this invention until ready to be used, at which time water is then added until an o/w emulsion has formed, which emulsion is then administered **orally or by injection**. Also, the stored w/o

microemulsion can be administered to the body wherein it is converted to an o/w emulsion by the addition of bodily fluids. In this manner, storage problems are lessened or eliminated.

Therefore, the microemulsions now claimed may be administered orally or by injection and be effective in administering the desired active agent, to include renin inhibitors.

4. ***Rejection Maintained, Claim Rejections - 35 USC § 103*** The rejection of claims 5, 9-25 under 35 U.S.C. 103(a) as being unpatentable over Silver et al as applied to claims 1-4, 6-8 and 26 above in view of Owen et al (US Pat. 5,633,226) is traversed on the grounds that "Owens is directed mainly at the formulation of peptides and protein not small molecules."

5. It is the position of the examiner that Silver et al describe and show compositions of microemulsions that comprise aliskiren, a gamma-amino-delta-hydroxy-omega-aryl-alkanoic acid amide rennin inhibitor, which is a small molecule. Silver et al teach the formulation of compositions that comprise a microemulsion. Owen et al was cited for teaching the advantages of convertible microemulsion formulations for "improved drug delivery systems" (see col. 2, lines 53-54) and are biologically compatible in that they are non-toxic and contain biodegradable or non-absorbable materials, which provide for significantly increase bioavailability of the delivered active agent (see col. 31, lines 7-9). Silver et al in view of Owen et al obviate the instantly claimed invention as now claimed as no unexpected results have been submitted to obviate the instantly claimed compositions and method.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the microemulsion of Silver with the microemulsion of Owen et

al because Owen et al teach the advantages of convertible microemulsions that provide for significantly increased bioavailability of the delivered active agent at the desired location.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining convertible microemulsions for the delivery of aliskiren, or another renin inhibit derivative thereof at taught by Silver et al because Owen et al teach that the microemulstion formulations are biologically compatible in that they are non-toxic and contain biodegradable or non-absorbable materials that are readily available for formulation into drug delivery compositions.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
August 6, 2007

MARK NAVARRO
PRIMARY EXAMINER